

REMARKS

The features of claim 1 are based on claims 1, 4, 5, 6 and 7 as originally filed. The feature that the mouthpiece is openably connected to part B is disclosed throughout the description and drawings (e.g. page 1, lines 32-33, page 2, lines 10-12, Fig. 1, 6).

Claim 2 is directed to the embodiment of the mouthpiece as disclosed in the description on page 2, lines 14-27 and Fig. 2.

The amendments to claim 3 are editorial.

Claims 4, 5, 6, and 7 have been incorporated into claim 1.

Claim 8 corresponds to claim 8 as originally filed.

Claim 9 corresponds to claim 9 as originally filed with the addition of a feature that is disclosed throughout the description and drawings.

Claim 10 is directed to a specific embodiment as disclosed on page 2, line 30 and Figures 3, 6.

Claim 11 is directed to the embodiment of the mouthpiece as disclosed in the description on page 2, lines 14-27 and Fig. 2.

Claims 12, 13, 18, 19 and 20 are directed to the embodiment of the blister strip as disclosed on page 2 lines 39-45 of the description and Fig. 5.

Claim 14 is directed to a specific embodiment as disclosed on page 2 lines 39-45 of the description and Fig. 5.

Claim 15 is directed to a specific embodiment as disclosed on page 2, line 30 and Figures 3, 6.

Dealing first with the 35 USC 102 rejection of claim 1, this has now been amended to incorporate the features of original claims 4, 5, 6 and 7. It is submitted that the claim is novel over the cited art. Newell European Patent Publication 0129985 discloses an inhaler that comprises a mouthpiece, a chamber whose top contains a cavity that supports a blister pack and a magazine for blister packs. However, the basic design of Newell differs from the present invention in that Newell is designed to release powder from its blister packs by puncturing them. The present invention is designed to release powder from blister packs by pulling apart the cover sheet and the base sheet of the blister pack. In Newell, when the inhaler is in use the blister pack is loaded on the support surface and the lid which is hinged at the rear end of the body of the inhaler is closed, thereby enabling a spike which is situated at the forward portion of the lid to pierce through the blister and to release the powder. The support surface of Newell therefore comprises only a cavity which accommodates the blister of the pack.

In contrast with the device described by Newell, the device of the present invention

comprises in addition to the cavity which is necessary to accommodate the blister, the additional features of the support surface of the device of the present invention contains an attachment point (13, 21, 24) and strip guides (15, 16). Furthermore, the mouthpiece is openably connected to the support surface and the cavity and guides are located such that exposure of the powder takes place by pulling away the cover sheet of the blister strip from the base sheet. This is totally different from piercing action required by Newell.

Claims 2 - 7 and 10 -20 share the same distinctions over Newell as claim 1.

So far as Claim 8 is concerned, the Examiner has suggested that Newell discloses all the features of the currently claimed blister strip. The applicant respectfully disagrees. Newell discloses a conventional blister strip comprised of a base sheet and a cover sheet, wherein the base sheet defines a powder containing blister. There is no additional feature at the base sheet of the blister strip, let alone an attachment formation as required by claim 8 of the present application. The currently claimed blister strip therefore is novel with regard to Newell.

Additionally, claim 8 is novel over Bonney (WO0064779). This discloses a single dose medicament carrier that is comprised of a **single sheet** which defines a first portion that forms a base sheet with a retainer for the containment of the product, and a second portion which is folded over to form the cover thereof. No means are provided to assist in securing the pack in a particular position in a device such as an inhaler so that the cover can be pulled off from the base. On the other hand, the single dose blister strip disclosed in the present invention comprises **two sheets**, the base sheet and the cover sheet, whereby the base sheet defines **two separate elements**, namely a **blister** and an **attachment formation**. Claim 8 (as well as claim 14 which is dependent on claim 8) is therefore novel over the prior art.

So far as claim 9 is concerned, this now defines the surface as being "of the inhaler" rather than simply being suitable for use in an inhaler. In the Examiner's report it is mentioned that Newell discloses an inhalation device for use with single dose blister strips which comprises a support surface with all the features of current claim 9. The applicant however does not agree with this statement.

As noted above, Newell discloses an inhaler that comprises a mouthpiece, a chamber whose top contains a cavity that supports a blister pack and a magazine for blister packs. When the inhaler is in use the blister pack is loaded on the support surface and the lid which is hinged at the rear end of the body of the inhaler is closed, therefore enabling a spike which is situated at the forward portion of the lid to pierce through the blister and to release the powder. The support surface of Newell therefore comprises only **one element**, i.e. a cavity which accommodates the blister. Similarly, Bonney discloses that the medicament pack is positioned into the device by accommodating the blister of pack into a holder, with no other means of attachment being suggested or hinted.

The support surface of the present invention on the other hand includes **three separate elements** i.e. a **cavity** which accommodates the blister, an **attachment point** (such as a protrusion) and **guides**. As it is stated in the specification, it is the presence of these three elements which enables the correct alignment and the secure attachment of the blister strip of the invention. Additionally, the support surface of claim 9 is suitable for use with a blister strip that contains an attachment formation at its base sheet, which is combined with the

corresponding attachment point of the surface. The only common feature therefore between the support surface of the present invention and the one of Newell is the cavity which accommodates the blister, and no novelty objection should arise with regard to claim 9. Additionally, claim 15 is also novel since it depends on claim 9.

Turning now to the issues raised under 35 USC 103(a), this is raised against only claim 2. There is, however, nothing in any of the cited art that points to the distinction noted above with respect to claim 1, on which claim 2 is dependent. The primary prior art reference, Newell, releases powder by puncturing the blister back. The present invention accomplishes this by pulling the cover and base sheets of the blister pack apart. This requires that the device has a means for securing the pack so that there is something to pull against and guides to position the blister pack to facilitate the necessary pulling. Nothing in any of the art points towards this. More specifically, the inhalation device of claim 1 comprises a specifically designed support surface (that of claim 9). This support surface is clearly different from and non-obvious over the cited prior art or any combination thereof. Bonney suggests that the housing of the inhaler includes a holder for the retainer of the medicament pack. Similarly, Newell discloses a surface with a cavity, which accommodates the blister of the medicament pack, and it does not suggest any other means for the attachment of the pack in the device. There is not a single suggestion throughout either Newell or Bonney that a further attachment point and/or guides are required in order to securely attach the medicament pack in the inhalation device. The holder (or the cavity) therefore is the only point of attachment for the medicament pack. Although this way of attachment is satisfactory for the inhaler disclosed in Newell (wherein the powder is exposed by way of a piercing force which is vertical to the blister of the pack), the same cannot be said for the inhaler of Bonney wherein the powder is exposed by exercising a force which is horizontal relative to the blister. The stabilisation of the pack in the inhaler, which is an essential precondition for the correct exposure of the powder in this case, cannot be guaranteed by merely placing the blister of the pack in a holder.

The support surface of the present invention on the other hand includes, further to the cavity which accommodates the blister, an attachment point (such as a protrusion) and guides. The attachment point, which is combined with a corresponding formation of the blister strip, acts as a means of resistance to the pulling force exercised during the exposure of the contents of the blister and guarantees that the blister strip will not be lifted from the support surface as a result of said force, something that will almost certainly occur in the case that the blister is the only point of attachment with the inhaler. Additionally, the guides secure the correct alignment of the medicament pack and eliminate the possibility of any movement of the pack along the support surface. The combination of the above elements on the support surface of the present invention offers superior stability of the blister strip in the inhaler, comparing to the prior art. The present invention addresses and solves the problem of the right and exact placement of the blister strip in the device by providing a support surface which further to the cavity it includes an attachment point which is combined with a corresponding attachment formation of the strip, and guides. Starting from Bonney, either alone or in combination with Newell, the person skilled in the art could not arrive at the support surface of the present invention in an obvious way. The subject matter of claim 9 therefore is not obvious over the prior art. This being the case, the inhaler of claim 1 and more specifically that of claim 2 is not obvious over the cited art.

For completeness and with a view to expediting prosecution, the applicants also point out that claim 8 is not obvious over any of the cited art taken singly or in combination either. Bonney is probably the closest art and this teaches away from the currently claimed blister pack, as it is clearly stated at the beginning of the document. The applicants of Bonney submit that blister packs that are comprised of two sheets for use with inhalation devices are well known in the prior art (lines 20-24), and that the object of their invention is "to provide a medicament carrier wherein the carrier comprised **a single sheet** or elongate strip thus providing significant advantages over the prior art in that the strip is straightforward to manufacture, providing both ease of use and reduction in manufacturing cost" (page 1, lines 24-28, emphasis added). Throughout the specification the applicants reiterate the importance of the single sheet in the design of their blister packs. There is no hint whatsoever that the disclosed invention **should** or even could be applied to a blister pack that is comprised of two sheets. On the contrary it is stated that the single sheet provides further advantages such as the possibility to form a multi-dose medicament carrier. The person skilled in the art therefore would not be inclined to take into consideration Bonney in order to design a single dose blister pack that is comprised of two sheets, let alone the one currently claimed.

Furthermore, the single sheet carrier described in Bonney comprises a first portion that forms a base sheet with a retainer for the containment of the product, and a second portion, which forms the cover thereof. The carrier is secured in the inhalation device by placing the retainer in a holder included in the housing of the device. There is not a single suggestion in Bonney that the carrier should include any additional elements in order to be securely attached to the inhaler. The only feature of the medicament pack that can be attached to an inhalation device is the powder containing retainer, which means that there is one mean of attachment between the medicament pack and the inhaler.

The currently claimed blister pack on the other hand is comprised of **two sheets** and the base sheet defines **both a blister and an attachment formation, e.g. a hole**, which are fixed at the corresponding points of an inhaler. The presence of both these elements on the base sheet of the claimed blister pack enables its total stabilisation in the inhaler, which is a very important feature, since it eliminates the possibility of the blister pack being moved out of its appropriate position during the process of exposing the content of the blister. This happens because the blister pack includes two means of attachment to the inhaler, i.e. the powder containing blister and the attachment formation (e.g. a hole). The applicant believes that the examiner will appreciate that a lack of stabilisation of the blister pack in the inhaler can cause a partial or even total failure of the exposure of the medicament contained in the blister, which entails a severe lack of efficacy of the inhaler.

Nothing in the prior art points to the provision of such stabilising means as are provided in the present invention. This is achieved by the presence of both the blister and the attachment formation on the base sheet of the strip. Bonney (either alone or in combination with Newell) does not give any motivation to the skilled person to arrive at the claimed

solution to the above problem, and therefore the subject matter of claim 8 (and claim 14) is not obvious.

In view of the foregoing, it is submitted that this application is in order for allowance and an early action to this end is respectfully solicited..

Respectfully submitted,



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